

false and misleading representations that the article was an adequate and effective treatment in controlling appetite, and causing one to lose weight immediately without tough diets; and, in addition, the display cartons contained statements that the article had just been released by the Federal Government for over the counter sale and that the article contained no harmful drugs, which statements were false and misleading since it contained the drug phenylpropanolamine which is not a harmless drug; certain precautions must be observed in its use; and such drug had not been "just released" but has been available for sale without prescription for a number of years under labeling which contains appropriate restrictions on the dosage and with caution against use by individuals with high blood pressure, heart disease, diabetes, and thyroid disease, except as directed by a physician.

DISPOSITION: 11-10-59. Default—destruction.

**6011. Alfex alfalfa tablets.** (F.D.C. No. 43151. S. No. 54-869 P.)

QUANTITY: 7 drums, each containing between 22,000 and 32,000 tablets and several hundred 30-tablet, 100-tablet, and 200-tablet btl. at Philadelphia, Pa., in possession of Shane Laboratories, Inc.

SHIPPED: 3-23-59, from North Kansas City, Mo.

LABEL IN PART: (Drum) "Alfex Tablets Concentration 29,000 \* \* \* Caution: For Repackaging Use Only"; (btl.) "Alfex Hi-Potency Alfalfa Extract 400 Mg. In Each Tablet \* \* \* Distributed by Shane Laboratories, Philadelphia \* \* \* Pa."

ACCOMPANYING LABELING: Leaflets entitled "A Message of Hope for Arthritic Sufferers"; a form letter headed "Dear Pharmacist"; a window display banner reading: "Pains? Stiffness? Why Suffer? Arthritis For Relief Take Alfex Tablets"; and a newspaper advertisement used as a counter display headed "Arthritis Sufferers At Last! Amazing Fast Relief from Arthritis-Sciatica-Rheumatism-Bursitis Alfex."

RESULTS OF INVESTIGATION: The tablets in the bottle were repackaged by Shane Laboratories, Inc., from bulk drums which were shipped as described above.

LIBELED: 5-21-59, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective in the treatment of arthritis, rheumatism, sciatica, and bursitis.

DISPOSITION: 8-19-59. Consent—claimed by Shane Laboratories, Inc., and reworked and relabeled.

**6012. Kank-A solution.** (F.D.C. No. 43277. S. No. 63-629 P.)

QUANTITY: 36 ctns., each containing one display card of 14 vials each, and 17 ctns., each containing one display card of 28 vials each, at Boston, Mass.

SHIPPED: 5-25-59 and 6-2-59, from Plymouth, N.H., by John Arthur Geyer Co.

LABEL IN PART: (Ctn.) "One Card Kank-A \* \* \* Mr. Druggist: Recommend Kank-A," (display card) "Use Kank-A," and (vial) "Kank-A \* \* \* Contents: Myrrh, Benzoin, S.D., Alcohol."

LIBELED: 6-23-59, Dist. Mass.; amended libel 6-24-59.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for canker sores and denture sores; 502(c)—the information required by the Act to appear on the labeling, namely, the common or usual names of the active

ingredients contained therein, a statement of the quantity of contents and adequate directions for use, was not prominently placed on the vial label of the article with such conspicuousness (as compared with other words, statements, designs and devices, in the labeling), as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein, since myrrh and benzoin were not declared by their common or usual names, and the proportion of alcohol contained in the article was not declared.

DISPOSITION: 7-22-59. Consent—claimed by John Arthur Geyer Co. and relabeled.

6013. Ree-vita tablets (vitamins). (F.D.C. No. 43285. S. No. 56-241 P.)

QUANTITY: 3,557 30-tablet vials at Kansas City, Mo., in possession of Dr. Reeves Products, Inc.

SHIPPED: 6-7-59, from Englewood, N.J., by Zenith Laboratories.

LABEL IN PART: (Vial) "Ree-Vita One Tablet Provides: \* \* \* Distributed by Dr. Reeves' Products, Inc. Kansas City 5, Mo."

ACCOMPANYING LABELING: Letters entitled "Dear Friend."

RESULTS OF INVESTIGATION: The "Dear Friend" letters were printed locally for Dr. Reeves Products and used for promoting sales of the article.

LIBELED: 6-30-59, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment to calm nerves; eliminate "jitters"; for neuritis-like pain; for regulating the bowels; to increase pep and energy, particularly of adults over 40 years of age; for skin disorders and anemia; to restore natural color to gray hair; and to control degenerative artery disease that attacks men over 40 and women after 55 years of age.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

DISPOSITION: 7-8-59. Consent—claimed by Dr. Reeves' Products, Inc., and relabeled.

6014. Dermathricin Aerospray. (F.D.C. No. 43035. S. No. 45-612 P.)

QUANTITY: 186 3-oz. cans and 217 6-oz. cans at Denver Colo.

SHIPPED: 12-22-58, from Houston, Tex., by Savage Laboratories, Inc.

LABEL IN PART: (Can) "Dermathricin Aerospray \* \* \* Contains \* \* \* Tyrothricin \* \* \* Hexadienol \* \* \* Benzocaine \* \* \* P-Chloro-M-Xylenol \* \* \* and Benzethonium Chloride \* \* \* Distributed by Arendt Laboratories, Denver 10, Colorado."

LIBELED: 5-29-59, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all types of burns, and all bacterial, viral, and fungus infections of skin, rectum, and vaginal mucosa.

DISPOSITION: 9-28-59. Consent—claimed by Arendt Laboratories, Denver, Colo., and relabeled.